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10/518,222

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Carlo A Dirusso

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HARRINGTON & SMITH, PC
4 RESEARCH DRIVE, Suite 202
SHELTON, CT 06484-6212

EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT

PAPER NUMBER

3739

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,222	Applicant(s) DIRUSSO ET AL.	
	Examiner MATTHEW J. KASZTEJNA	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the remarks filed on February 24, 2009, the current rejections of the claims *withdrawn* and the finality of the Office Action mailed December 22, 2008 is *withdrawn*. The following new grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,383,852 to Stevens-Wright.

In regard to claim 11, Stevens-Wright disclose an apparatus comprising: a handle 12; and a shaft 10 extending from the handle, the shaft comprising a front end with a first active deflection section 16 connected in series with a second active deflection 15 section, the control section 12 being adapted to independently deflect the first and second deflection sections, wherein the first and second active deflection sections are *adapted* to deflect such that a distal end of the apparatus *can be* placed in a calyx of a lower pole of a kidney without the need to passively deflecting the front end of the shaft against tissue of the kidney of a patient to reach the calyx of the lower pole, and wherein the first and second active deflection sections are each limited to deflection in a single common plane relative to each other (see Fig. 2 and Col. 4, Lines 4-30). The

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words “adapted to” and “can be” in the claim may be properly interpreted as “capable of,” and “capable of” does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use. If the prior art structure is capable of performing the intended use, then it meets the claim. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In regard to claim 12, Stevens-Wright disclose an appratus wherein the first active deflection section is adapted to deflect through an angle of about 180° to about 210° (see Col. 4, Lines 19-20).

In regard to claims 13-14, Stevens-Wright teach of a brake actuator located on the handle adapted to lock one of the active deflection sections at a desired position as a friction pad 150 functions to provide constant friction during sliding movement of the slider 140 and the slider grip 152 so that any desired position is maintained until the friction of the friction pad 150 is overcome, e.g., by physically repositioning the slider grip 152 (see Fig. 14 and Col. 10, Lines 40-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,938,588 to Grabover et al. in view of U.S. Patent No. 5,383,852 to Stevens-Wright.

In regard to claims 1 and 19-20, Grabover et al. disclose an endoscope comprising: a handle 12; and a shaft 14 extending from the handle, the shaft having a front end comprising a first active deflection section 18 including a plurality of rings 40 pivotably connected to each other wherein the first active deflection section is limited to deflection in a first plane (see Fig. 2 and Col. 2, Lines 48-55). Grabover et al. teach that the control system may have two or more pairs of control wires, and wherein the handle may have additional actuators and corresponding controls to drive the additional pairs of control wires. However, Grabover et al. are silent a second active deflection section including a plurality of rings pivotably connected to each other, wherein the second active deflection section is limited to deflection in a second different plane, and wherein the first plane is angled to the second plane. Stevens-Wright teach of an analogous endoscopic apparatus wherein two pull cables 32a and 32c (referred to in this description as a horizontal pull-cable pair) are used to control bending of a proximal section 15 within a horizontal plane of orientation as shown diagrammatically in FIG. 2. The other two pull cables 32b and 32d (referred to in this description as a vertical pull-cable pair) are used to control bending of a distal section 16 within a vertical plane of orientation (see Col. 4, Lines 4-15). **In regard to claims 2-4 and 6**, Stevens-Wright teach that the relative orientation between these two planes may vary with different

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catheter applications and desired tip-shapes and the two planes may form angles between zero degrees and one hundred eighty degrees. By varying the angle of intersection between the two planes, one catheter tip arrangement, for example a two-dimensional arrangement (where both planes are coplanar), may be bent into a specific shape (such as a spiral) within the single plane of movement. If the first and second planes of orientation of the respective proximal and distal bending movements intersect at ninety degrees (as illustrated in FIG. 2), the resulting catheter tip may be manipulated into several two and three-dimensional shapes including a three-dimensional spiral cone (see Col. 4, Lines 15-30). **In regard to claims 7-8**, Stevens-Wright teach of a brake actuator located on the handle adapted to lock one of the active deflection sections at a desired position as a friction pad 150 functions to provide constant friction during sliding movement of the slider 140 and the slider grip 152 so that any desired position is maintained until the friction of the friction pad 150 is overcome, e.g., by physically repositioning the slider grip 152 (see Fig. 14 and Col. 10, Lines 40-55). It would have been obvious to one skilled in the art to provide a second active deflection section in the apparatus of Grabover et al. to provide left-right proximal bending and up-down distal bending of the tip assembly and thus allowing for manipulation of the tip assembly into several two and three-dimensional shapes including a three-dimensional spiral as taught by Stevens-Wright.

In regard to claim 5, Grabover et al. disclose an endoscope, wherein the first active is adapted to deflect through an angle of about 110° to about 220° (see Col. 3, Lines 20-25).

In regard to claim 9, Grabover et al. disclose an endoscope, wherein the endoscope comprises a cystoscope comprising means 37 for viewing 360° inside of a generally spherical shape through a fixed entrance into the generally spherical shape by a camera or an optical lens at the front end of the shaft without axially rotating the shaft (see Fig. 3 and Col. 3, Lines 1-5).

In regard to claim 10, Grabover et al. disclose an endoscope, wherein the first active deflection section comprises rings 40 pivotably connected to each other to form a frame of the first active deflection section, wherein a connection of the rings to each other comprises balls located in sockets of the rings and at least one connecting member extending through a hole in the balls (see Col. 3, Lines 15-36).

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,383,852 to Stevens-Wright in view of U.S. Patent No. 5,938,588 to Grabover et al.

In regard to claims 15-17, Stevens-Wright discloses an apparatus comprising: a handle 12; and a shaft 10 extending from the handle, the shaft comprising a front end with a first active deflection section 16 connected in series with a second active deflection 15 section (as rejected above) but is silent with respect to first and second shape-memory frame members having a general tubular shape comprised of a superelastic material. Grabover et al. teach of an analogous apparatus provided with a handle and a flexible shaft connected to the handle. The flexible shaft has a passive deflection section and an active deflection section operated by a control wire. The passive deflection section has a sheath holding a portion of the control wire therein.

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The sheath is made from a superelastic alloy material and is resiliently deflectable to bend with the passive deflection section without permanent deformation or substantial fatigue over a working life of the endoscope. The sheath has continuous column strength to support axial loads without cross-sectional and longitudinal deformation or loss of flexibility (see Figs. 2-3 and Col. 4, Lines 7-67). It would have been obvious to one skilled in the art at the time the invention was made to provide first and second shape-memory frame members having a general tubular shape comprised of a superelastic material in the apparatus of Stevens-Wright to enhance the accuracy and total deflection of the active deflection section as taught by Grabover et al.

Response to Arguments

Applicant's arguments with respect to claims 1-17 and 19-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./
Examiner, Art Unit 3739

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